WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA722 trade name]*

Dolutegravir (as sodium) /lamivudine/tenofovir disoproxil fumarate
50 mg/300 mg/300 mg tablets

[HA722 trade name], manufactured at Emcure Pharmaceuticals Limited, Pune, Maharashtra, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 22 February 2021.

[HA722 trade name] is indicated for the treatment of human immunodeficiency virus (HIV) infection in adults and adolescents weighing at least 30 kg. It may also be used in these patients for post-exposure prophylaxis to HIV Detailed information on the use of this product is described in the summary of product characteristics (SmPC), which can be found in this WHOPAR.

The active pharmaceutical ingredients of [HA722 trade name] are dolutegravir (as sodium), lamivudine and tenofovir disoproxil fumarate.

The efficacy and safety of dolutegravir (as sodium), lamivudine and tenofovir disoproxil fumarate are well established based on extensive clinical experience in the treatment of HIV/AIDS.

For details on the uses of this product and for side effects and warnings, see Part 4 of this WHOPAR (summary of product characteristics).

On the basis of data submitted and public information on the use of dolutegravir (as sodium), lamivudine and tenofovir disoproxil fumarate in HIV/AIDS, the team of assessors advised that [HA722 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA722 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA722 trade name]:

The table shows the status of relevant completed activities, including the dates of WHO internal quality assurance.

Initial acceptance	**Date**	**Outcome**
Status on PQ list	22 February 2021	listed
Pharmaceutical quality	18 February 2021	MR
Bioequivalence	19 February 2021	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
APIs	07 September 2017	MR
API	26 August 2019	MR
FPP	15 February 2019	MR
GCP/GLP (re-)inspection	16 July 2020	MR*:

API: active pharmaceutical ingredient
FPP: finished pharmaceutical product
GCP: good clinical practice [quality standard]
GLP: good laboratory practice [quality standard]
GMP: good manufacturing practice [quality standard]
MR: meets requirements
MR*: desk review (based on recent inspection reports)
NA: not applicable, not available
PQ: prequalification

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.